American Academy of Physician Assistants

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TESTIMONY OF

THE AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS

SUBMITTED TO

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
TASK FORCE ON DRUG IMPORTATION

May 14, 2004

Surgeon General Carmona and members of the task force, on behalf of the more than 51,000 clinically practicing physician assistants in the United States, the American Academy of Physician Assistants is pleased to comment on the important issue of drug importation. Thank you for the opportunity to share with you the perspective of physician assistants on this important topic.

In 2003, approximately 192 million patient visits were made to physician assistants (PAs) and approximately 236 million medications were prescribed or recommended by PAs. PAs work in every specialty and in every practice setting in every state and care for patients of all ages. Over 20% of PAs work in rural or underserved areas.

What all those PAs have in common is a commitment to providing quality, cost-effective and accessible health care. That is, in fact, the Academy's mission statement and it will guide our remarks on the issue before you. While AAPA has no specific policy on drug importation we do have several related policies.

?? The Academy supports a Medicare prescription drug benefit plan that is universal, mandatory for all beneficiaries, integrated into the basic benefit package, is not a financial hardship to beneficiaries, includes catastrophic coverage, has a defined, comprehensive benefit, and permits health care providers to select medications using appropriate medical judgment that includes consideration of cost effectiveness, safety, and efficacy.

?? The Academy supports legislative efforts to block the diversion of prescription drugs to illicit channels and prevent the sale or trade of samples, while preserving appropriate access by physicians, physician assistants, and other appropriate health care practitioners to samples of prescription drugs from pharmaceutical manufacturers.

?? The Academy believes that all physician assistants should become knowledgeable of programs sponsored by local governments, the private sector, and pharmaceutical companies that make available prescription medications free of charge or at a reduced cost for underinsured, uninsured, and underserved patients.

For physician assistants, the focus is on the patient. PAs understand that consumers and state purchasers need affordable drugs. PAs understand that the pharmaceutical industry and distributors want to insure safety as well as incentives for future drug development. In the world our members live in the argument seems to be framed as, "what trade-offs are we willing to accept to balance safety and affordability?" Ensuring a safe and genuine drug supply is critical but so is assuring an accessible one. Safe drugs that are unaffordable are of no benefit to those who need them the most. I know it is cliché and anecdotal but many PAs have shared with me their stories of patients who must often choose between their medications or their groceries.

I have spoken with PAs in Maine, Seattle, Detroit, and others. They tell stories of how their older patients get on buses on the weekends to drive to Canada to buy their drugs. It's the only way they can afford them. One of our members described it this way: "Who do you think is going to Canada to get their drugs? Do you think it is the insured patient with a pharmacy card who for $20 can pick up their prescription for

Lipitor at the local pharmacy? No, it is the fixed income senior or working uninsured person who is heading across the border to essentially pay cash for their prescription because there is no other way." PAs in Texas and California share similar stories about their patients who travel to Mexico.

Our patients are buying brand name drugs. They are not going across the border to buy generics. The drugs are manufactured to the same standards and are often in the same packaging as the drugs sold in the U.S. Are Canadians suffering any dire consequences due to unsafe drugs in their system? It doesn't seem to be so.

Clearly, there are issues of safety to consider. Unsafe, counterfeit drugs appear to enter the system when the traditional distribution system breaks down. When retailers or distributors buy drugs through other channels or consumers purchase their drugs through Internet pharmacies the supply is at risk. PAs generally do not recommend that their patients buy drugs over the Internet unless they know the site has a reputation for providing quality products.

It begs the question again, "who is most likely to purchase drugs from an Internet pharmacy. Who is most vulnerable to be scammed with the counterfeit, ineffective or unsafe medications some of these sites provide?" Again, I think the answer is likely those on low fixed incomes or the uninsured. The demand for less expensive sources of medications has also paralleled the growth in the number of uninsured in the U.S. which the Institute of Medicine estimates to be 43 million persons.

We appreciate the efforts of some pharmaceutical companies to make available discounted drugs to the poorest patients who need them. We are optimistic that the new Medicare discount drug card will assist some of our seniors in affording the drugs they need. We appreciate the viewpoint of many governors that Canada or Europe offers some solutions to an immediate financial crisis. However, the problem of unaffordable drugs is just one symptom of our ailing health system. Making health care, in general, more affordable, more accessible and safer is a larger problem beyond the jurisdiction of this task force but a context for your recommendations that cannot, it seem, be ignored.

At best, allowing importation from Canada or other industrial countries is a limited solution to those broader problems. There need to be more permanent solutions to the inequities of drug pricing. Especially since from the perspective of physician assistants the people who are paying the most for their medications are the ones who can least afford it.

There are other potential fixes like giving consumers the ability to order directly from wholesalers. States could be creative in finding ways to negotiate Canada-like prices for drugs. We are not the experts on those solutions, we are experts on patient care, we know patient care. We need patients to be able to obtain the drugs they need at a price they can afford. The safest drug in the world does not help the patient who cannot afford to take it.

Recently, the Academy has been focusing on ways to improve patient adherence. Last month, the Academy brought together experts on patient adherence including representatives from the Surgeon General's office to discuss the state-of-the-art and begin to set a research agenda. All health professionals know that adherence by patients to the therapeutic plan is a crucial part of improving health. PA students

learn the "four Ms" of nonadherence: misunderstanding, motivation, medication, and money. What this tells us is that even if we improved patient-provider communication and health literacy, even if we motivated patients to become healthier, even if we designed drugs that had no untoward side effects, we would still have a problem if the drug were not affordable.

Physician assistants feel strongly about their role as patient advocates. Whatever recommendations you make, we would encourage them to be patient-centered. Patient-centeredness is just one aim of the ideal health system envisioned by the Institute of Medicine in its landmark report on the healthcare system. The other aims for a 21st century healthcare system are equally applicable to our drug supply. It should be safe, effective, timely, efficient and equitable.

Patients don't just need medicines that are either safe or affordable; they need medicines that are both safe and affordable. Finding ways to achieve that will diminish the need for our poorest patient to go to Canada or Mexico or be taken by Internet scams.

Thank you for the opportunity to present the American Academy of Physician Assistants' view on drug importation. The issues you face are extraordinarily complex and we commend you for your work. Please do not hesitate to contact us if we can be of any further assistance.

AAPA's Response to Drug Importation Task Force Questions

I. Scope and volume of imported drugs

Non-FDA approved drugs should not be allowed for reimportation. At this point, importation should be limited to FDA approved drugs manufactured to U.S. specifications either personally transported or imported through a trustworthy entity. FDA could provide information to consumers about which entities were "trustworthy." It is highly likely that importation would be limited to the most expensive brand drugs. If a generic version existed then the drug would be a less likely target for import. Additionally, chronic use medication are likely targets for importation. Although some PAs are a little hesitant to support the importation of controlled substances (especially schedule II and III), there is no specific evidence which supports different importation rules for these drugs.

II. Impact on pharmaceutical distribution system

The distribution chain still needs to be explicit and traceable. There is evidence that even in the U.S. when the distribution chain becomes long and convoluted; it is more susceptible to the introduction of counterfeit and unsafe medications. Limiting importation to trustworthy sources that have been recognized by FDA for their conformity to such standards would be desireable.

III. Extent to which foreign health agencies are able to ensure safety

It seems reasonable to limit importation to countries that are committed to FDA-like safety and accountability of their nation's pharmaceutical supply.

IV. Identify the limitations on the secretary's ability to certify safety

Drugs that are not FDA-approved and do not have a traceable supply chain cannot be certified as safe.

V. Estimate agency resources to inspect pharmaceuticals entering the country

By setting up a system whereby entities apply to be trustworthy importers, resources would only be needed to investigate and monitor those few importers.

VI. Identify ways in which importation could violate intellectual property rights

By importing only U.S. approved medications, intellectual property rights would be preserved.

VII. Estimate the costs borne by entities within the distribution chain to provide security

One could argue that no additional costs are necessary other than those that should already be in place to protect the security of the distribution chain from the entry of counterfeit drugs. Those same technologies will need to be implemented in the U.S. distribution chain as well.

VIII. Assess the potential short- and long-term impact on drug prices and prices for consumers associated with importing drugs from other countries

Currently, it is estimated that Americans are spending $1 billion dollars buying drugs from Canada. That represents considerable interest by consumers in saving money. In the U.S. favored customers pay about half of what individuals buying their drugs at retail prices pay. Even with additional costs for security importing drugs it is likely there would still be substantive savings for seniors and uninsured patients. The cost savings of importation will only disappear when all consumers can get the benefit of favored customers and others, like Canada, that have negotiated significantly lower prices for drugs.

IX. Assess the impact on drug research and development if importation were permitted

It has become very expensive for pharmaceutical companies to bring drugs to market. It is understandable that companies need to generate funds to continue research and development. However, it seems that companies have focused on more and more expensive blockbuster drugs over the years and are less committed to developing drugs that have substantial impact but less return on investment, like vaccines for example. Companies also spend a great deal on marketing. Until true and equitable pricing plans are in place it is unclear what the impact will be on research and development.

X. Identify the liability protections that should be in place if importation is permitted

The same liability protections should be in place that currently exist for the U.S. drug distribution system. If a importation pharmacy dispenses the wrong medication, they should be liable as a U.S. pharmacy would be. The same holds true if a counterfeit drug gets into the import distribution chain, the distributers as well as the counterfeiters should be liable.

XI. Analyze whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those which are imported

At this point, the magnitude of the counterfeit drug problem in the U.S. seems rather small. Again, the key to minimizing the problem is having a clear distribution chain. Internet pharmacies without a clear distribution chain may give rise to the problem. However, the demand for Internet pharmacies would be lessened with more equitable drug pricing.